

CLAIMS

1. Safety apparatus for transfusions of blood or blood derivatives contained inside at least one bag (1) having at the bottom at least one tube (2) made of elastically deformable material such as rubber or the like, for discharging the blood or blood derivatives, said blood or blood derivatives belonging to a given blood group with an associated Rh factor, characterized in that it comprises a constriction device (3; 74) closed by suitable clamping means (14, 15; 77, 78) movable about said tube (2) so as to prevent the blood or blood derivatives which leave the bag (1) from passing through said tube (2), said constriction device (3; 74) being provided with a seat (4) on which suitable elements (6, 7; 79) for coding and identifying said blood group with associated Rh factor are formed, which elements co-operate with a unique key (19; 66) for opening, in the event of compatibility, said constriction device (3; 74) provided with suitable elements (5, 21, 22; 67, 68) complementing said coding elements (6, 7; 79) and able to release said clamping means (14, 15; 77, 78) so as to open said constriction device (3; 74) and free said tube (2).
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2. Apparatus according to Claim 1, characterized in that said constriction device (3; 74) is connected in an irreversible manner and using suitable means (12) to said bag (1), both in said position closed by said clamping means (14, 15; 77, 78) and in said open position with said clamping means (14, 15; 77, 78) unlocked.
3. Apparatus according to Claim 1, characterized in that said opening key (19; 66), used to check the identity of the patient's blood group and its compatibility to the receivable blood, is placed inside a seat (25; 45) formed in a wrist-band (24) fixed to the wrist of a patient who is required to undergo a given operation.
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4. Apparatus according to Claim 1, characterized in that said bag (1), said constriction device (3; 74), said opening key (19; 66) and said wrist-band (24) bear the same writing (43) identifying the blood group with associated Rh factor of the patient.
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5. Apparatus according to Claim 1, characterized in that opening keys (19; 66) indicating the blood group of the patient and the groups compatible with that of the patient are placed inside said seat (25; 45) of the wrist-band (24).
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6. Apparatus according to Claim 1, characterized in that said constriction device (3; 74) comprises a central disk (4) having, arranged thereon in a precise position, projecting teeth (6, 7; 79) co-operating with through-holes (21, 22; 67, 68) complementing said projecting teeth (6, 7; 79) and formed in a similar position on a
5 tag (19; 66) for opening said constriction device (3; 74).
7. Apparatus according to Claim 6, characterized in that said central disk (4) comprises a raised annular edge (8; 75).
8. Apparatus according to Claim 7, characterized in that a projecting reference stud (9; 82) co-operating with an incision (20; 73) formed in the edge of said opening
10 tag (19) is provided in the vicinity of the inner wall of said raised annular edge (8; 75) of the central disk (4).
9. Apparatus according to claim 8, in which the said reference stud (82) and the cooperating incision (73) have both a complementary asymmetrical profile.
10. Apparatus according to Claim 6, characterized in that an arm-piece (14) foldable towards the rear of said central disk (4) by means of a suitable hinge (16) is fixed or formed integrally on one side of said central disk (4), the free end of said
15 arm-piece (14) comprising a ratchet pin (15) inserted inside a through-hole (5) formed in said central disk (4) for closing said constriction device (3) and clamping said tube (2).
- 20 11. Apparatus according to Claim 10, characterized in that said hinge is a weakened zone (16) formed in the vicinity of the end of the arm-piece (14) connected to said central disk (4).
12. Apparatus according to Claim 10, characterized in that said opening tag (19) comprises a substantially frustoconical through-hole (23) for releasing by means of
25 pressure said ratchet pin (15) and for opening said constriction device (3).
13. Apparatus according to Claim 10, characterized in that said central disk (4) has at the rear a seat (17) inside which said tube (2) is positioned and clamped between said arm-piece (14) and said seat (17).
14. Apparatus according to Claim 13, characterized in that said seat (17)
30 comprises a series of transverse ribs (18).

15. Apparatus according to Claim 10, characterized in that the central disk (4) is provided on the side opposite to that where said arm-piece (14) is connected with a projecting lug (10) having, formed thereon, a hole (11) for fastening a tie (12) for fixing in an irreversible manner said constriction device (3) to said bag (1).
- 5 16. Apparatus according to Claim 6, in which the said constriction device (74) is further provided with a substantially cylindrical lid (83), firmly connected to the said constriction device (74), provided with an opening (85, 89) for the introduction of the said tag, the said opening being provided with means for coding (90) the said introduction, said means for coding (90) cooperating with complementary coding 10 means provided on the said tag (66).
17. Apparatus according to claim 16, in which the said opening comprise a slot (85) provided radially on the lateral wall (84) of the said lid (83).
18. Apparatus according to claim 17, in which the said means for coding the introduction comprise one or more grooves (90) formed at one edge of the said slot 15 (85), the corresponding tag (66) being provided with ribs compatible with the design of the said grooves (90).
19. Apparatus according to Claim 16, in which the said lid (83) comprise means for pushing (87) the said tag (66) against the said central disk (4).
20. Apparatus according to Claim 3, characterized in that said wrist-band (24) comprises a face-plate (25; 45) with, formed thereon, projecting teeth (31, 32; 52) having a shape and position corresponding to the through-holes (21, 22; 67) formed in said tag (19; 66).
- 25 21. Apparatus according to Claim 20, characterized in that said face-plate (25) comprises a further cylindrical pin (33) with which said substantially frustoconical hole (23) formed in said opening tag (19) can be engaged.
22. Apparatus according to Claim 20, characterized in that said face-plate (25; 45) comprises a raised annular edge (29; 55) for receiving therein several opening tags (19; 66) of the same type stacked on top of one another, the number of said stacked tags (19; 66) corresponding to the number of bags (1) with blood or blood derivatives 30 of a same blood group, required by the patient.

23. Apparatus according to Claim 22, characterized in that a projecting reference stud (34; 53) complementing said incision (20; 73) formed in the opening tag (19; 66) is provided on the inner wall of said annular edge (29; 55) of the face-plate (25; 45).
- 5 24. Apparatus according to Claim 23, in which the said reference stud (53) and the complementing incision (73) have both a complementary asymmetrical profile.
25. Apparatus according to Claim 22, characterized in that the raised annular edge (29) of said face-plate (25) comprises one or more openings (30) for facilitating extraction and for checking the number of tags (19) stacked inside the wrist-band (24).
- 10 26. Apparatus according to Claim 20, characterized in that said wrist-band (24) comprises a strap (28) for fastening to the patient's wrist, two lugs (26) being formed on two opposite sides of the face-plate (25) and being each provided with at least one slit (27) through which said strap (28) passes.
- 15 27. Apparatus according to Claim 26, characterized in that each of said lugs (26) is provided with a projecting pin (36) and said strap (28) is provided on both opposite sides of the face-plate (25) with a series of through-holes (44), each projecting pin (36) being inserted inside one of said through-holes (44) of the strap (28) and said projecting pin (36) being engaged by suitable elements (35) able to permanently fix the strap (28) to the face-plate (25) and connected by means of flexible bands (37) to 20 said face-plate (25).
28. Apparatus according to Claim 20, characterized in that said face-plate (25) comprises a closing cover (38).
29. Apparatus according to Claim 28, characterized in that said closing cover (38) comprises an annular edge (39) provided with a series of divisions (40) or weakened zones suitable for facilitating extraction of the tag with a movement performed by 25 means of pressure or rotation.
30. Apparatus according to Claim 28, characterized in that said cover (38) comprises internally a projecting tooth (42) having a shape and position corresponding to one of the through-holes (21) formed in the opening tag (19) so as 30 to ensure positioning with the writing indicating the blood group directed downwards.

31. Apparatus according to Claim 28, characterized in that said cover (38) comprises on its periphery one or more rings (41) for connection to the body of said face-plate (25).

32. Apparatus according to Claim 19, in which the said closing cover (60) is provided with a diaphragm (64) formed almost centrally in its closing plate, the said diaphragm (64) being able to cooperate with an extraction member (58) which can be inserted through the same diaphragm so as to extract the tag(s) (66) from the said cover (60).

33. Apparatus according to Claim 32, in which the said extraction member comprise a stud (58) placed axially at the center of a cap (57), the said cap (57) being couplable to the said cover (60), and being also firmly connected to the said face-plate (45).

34. Apparatus according to Claim 32, in which the said diaphragm (64) is provided with one or more fracture weakenings (65).

35. Apparatus according to Claim 32, in which the said cover (60) comprises internally a projecting tooth (61) having a shape and position corresponding to one of the through-holes (67) formed in the opening tag (66).

36. Method for using the safety apparatus for transfusions of blood or blood derivatives according to any one of the preceding claims, characterized by the following steps:

- a) establishing the blood group with associated Rh factor contained inside a given bag (1);
- b) recording on said bag (1) information (43) indicating said blood group with associated Rh factor;
- c) mounting the constriction device (3) with the same information (43) on the tube (2) for discharging the blood or blood derivatives from said bag (1);
- d) connecting in an irreversible manner the chosen constriction device (3) to said bag (1);
- e) identifying the blood group with associated Rh factor of the patient and recording the data obtained in a hospital file and on a tab to be attached to the wrist-band (24)

fastened to the patient's wrist;

f) choosing the face-plate (25) with information (43) as to the blood group and associated Rh factor corresponding to that of the patient;

g) fixing the face-plate (25) permanently to the strap (28);

5 h) fastening the wrist-band (24) to the patient's wrist;

i) selecting the number of bags (1) to be transfused, containing blood or blood derivatives with a blood group and associated Rh factor established beforehand and required by the patient;

j) choosing the number and type of tags (19) corresponding to the blood group of the patient according to the number of bags (1) required or associating with each individual bag a tag already inserted inside the cover;

k) placing the chosen tag (19) or tags (19) so that they are stacked on the face-plate (25) of the wrist-band (24) or releasing the tag from the cover by means of pressure or rotation;

15 l) removing, at the time of the operation to be carried out on the patient, the tag or tags (19) present in the wrist-band (24) and opening the corresponding constriction device or devices (3), i.e. one for each tag (19).

37. Method according to Claim 36, characterized in that the abovementioned steps a), b), c), d), e), f), g), k) and l) are carried out in a transfusion centre outside the hospital department where the patient is waiting to be operated on.

20 38. Method according to Claim 36, characterized in that the steps d), e), h), k) and l) are carried out in the department of the hospital where the patient is waiting to be operated on or where the transfusion is performed.

39. Method according to Claim 36, characterized in that a further step involving 25 checking and cross-checking of the patient's blood group and the blood group of the bags to be transfused is envisaged between the step g) and the step h).

40. Method according to Claim 36, characterized in that said wrist-band (24) is fastened to the patient upon admission to the hospital and, after step e), the face-plate (25) with the information (43) indicating the corresponding blood group and 30 associated Rh factor is fixed thereto in an irreversible manner.

41. Safety apparatus according to Claims 1 to 35 for implementing the method according to Claims 36 to 40, characterized furthermore by the fact that it is possible to provide each person concerned with an individual tag (19; 66), to be carried on them at all times, coded in a manner corresponding to the blood type of the owner so that, in the event of admission to hospital in order to undergo a blood transfusion, the user is able to check whether the elements coding and identifying his/her blood group and associated Rh factor assigned to said face-plate (25; 45) actually correspond to those on their own tag.